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Proposed Maximum Residue Limit PMRL2016-60

Spinetoram

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Delegate WP Insecticide, containing technical grade spinetoram, is acceptable. The specific uses approved in Canada are detailed on the label of Delegate WP Insecticide, *Pest Control Products Act* Registration Number 28778.

The evaluation of this spinetoram application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spinetoram is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to replace or be added to the MRLs already established for spinetoram, are as follows:

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Spinetoram	XDE-175-J: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-	22	Dried basil leaves
		6.0	Fresh basil leaves
		0.9	Dill seeds

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
	yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*) and XDE-175-L: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-(2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*), including the metabolites N-demethyl-175-J: (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13-{[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino)tetrahydro-2*H*-pyran-2-yl]oxy}-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-2-yl 6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranoside and N-formyl-175-J: (2*R*,3*S*,6*S*)-6-({(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide	0.3[2]	Peaches, nectarines

[1] ppm = parts per million

[2] The MRL of 0.3 ppm is proposed to replace the currently established MRL of 0.2 ppm in/on nectarines and peaches.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs, proposed for spinetoram in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Dill seed	0.9	1.7 (Spices, crop subgroup 19B, except black pepper)	Not established
Dried basil leaves	22	22 (Herb, dried, crop subgroup 19A)	Not established
Fresh basil leaves	6.0	3.0 (Herbs, fresh, crop subgroup 19A)	Not established
Nectarines and peaches	0.3	0.3 (Fruit, stone, crop group 12-12)	0.3

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinetoram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for spinosad in basil, dill and peaches were submitted to support the domestic use of Delegate WP Insecticide on these crops.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spinetoram was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for basil, dill, peaches and nectarines.

Table A1 Summary of Field Trial Data Used to Support the MRLs

Commodity	Application Method/ Total Application Rate (g a.i./ha)[1]	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)
Basil (fresh)	Foliar/ 519-557	1	0.55	1.85
Basil (dry)	Foliar/ 557	1	6.3	6.3
Dill seed	Foliar/ 473-526	13-15	<0.02	0.35
Peaches	Foliar/ 552 – 571	1	0.049	0.130

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of spinetoram. Residues of spinetoram on these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.